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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,704	09/30/2004	Sean P. Selover	101896-0283	5703
21125 7590 07/29/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER SWIGER III, JAMES L.	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 07/29/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary**Application No.**

10/711,704

Applicant(s)

SELOVER ET AL.

Examiner

JAMES L. SWIGER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/23/2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 5, applicant claims the step of separation of "the muscles." However, previously, there is no identification of "the muscles," per se. Applicant claims identifying *a muscle plane*, which can then be understood to be *the* muscle plane in line 5 that must be moved by a blunt tip tool. However, the identification of a plane does not necessarily define "the muscles" which is claimed in the method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Landry et al. (US Publication 2004/00143265). Landry et al. disclose a minimally invasive method comprising the steps of forming an incision that is minimally invasive and percutaneous located adjacent a person's vertebra (see abstract for procedure near spine), identifying a muscle plane (see par 0024) which helps to minimize trauma as a plane may be formed without severing muscle tissue, inserting a blunt-type tool (pars 0017 and 0237) which again assist in minimizing trauma to the spinal area. The tool may also have a blunt-type blade which is considered substantially planar.

Claims 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Teitelbaum (US Patent 6,821,277). Teitelbaum discloses a minimally invasive surgical method comprising the steps of making an incision in a patient (see Fig. 13, through the skin), inserting a blunt tip tool (202) through the skin to create a pathway between muscle. It is noted that the disclosed biopsy needle may also have an equivalent structure in size to access the area required by the surgery. Teitelbaum also discloses the step of inserting a guidewire through the tool adjacent a first site (see Fig. 11). Teitelbaum further discloses removing a tool (Fig. 13) and inserting an implant such as a screw along a guidewire to a first site on a surgical body (see Fig. 13), making a second incision and having another implant guided along a guidewire (Fig. 16). Teitelbaum also discloses inserting a fixation element (216/222/220) through a first and second pathways and which is then coupled to the first and second implants. At least a

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portion of this fixation element is substantially parallel to the longitudinal orientation of the first pathway.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landry et al. '265 in view of Hamada (US Patent 6,849,064). Landry et al. disclose the claimed method except for the steps of separating specifically the longissimus thoracis and multifidus muscles. Hamada discloses access to a spinal area via the above mentioned muscle planes because they are the most direct approach to the spinal area through an avascular plan, thus preventing extensive muscle injury and "fibrotic muscle." It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method as taught by Landry et al. further teaching the step of accessing the spinal through the muscle plane created by the above two muscles as taught by Hamada to prevent extensive muscle injury.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landry et al. '265 in view of Teitelbaum. Landry et al. disclose the claimed invention except for the step of inserting a guidewire through a blunt tip tool, extending the wire to the vertebra and then inserting a screw or implant over the guidewire. See above rejection for further details providing the wire and implant structures. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Landry et al. having at least the steps involving the guidewire, blunt tip and implant apparatus as taught by Teitelbaum to have more controlled access to the spinal area when inserting the implant, as the implant is already guided by a non-visual means.

Claims 8-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Landry and Teitelbaum as applied to claim 6 above and further in view of Gitis et al. (US Publication 2003/0216768). The combination of Landry et al. and Teitelbaum disclose the claimed method except for the steps of using a plurality of dilators to assist inserting the spinal anchors. Gitis et al. shows multiple dilators (see Figs. 9-12). See also pars 0049 - 0052. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Landry et al. and Teitelbaum having at least the step of expanding dilators as taught by Gitis et al. to have a larger work area as required by the patent and surgical procedure, and for making this expanded incision with as little trauma as possible.

Response to Arguments and Finality

Applicant's arguments, see appeal brief, filed 3/27/2008, with respect to the rejection(s) of claim(s) 1-17 under Shluzas et al. (US patent 7,179,225) have been fully considered and are persuasive after a conference was held on 6/12/2008. Therefore, the rejection and finality has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the above references.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

